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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,471	10/19/2001	Martin T. Martin	100391-02030	1031

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KRAMER LEVIN NAFTALIS & FRANKEL LLP
INTELLECTUAL PROPERTY DEPARTMENT
1177 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER	
PATTERSON, CHARLES L JR	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/039,471	MARTIN, MARTIN T.	
	Examiner	Art Unit	
	Charles L. Patterson, Jr.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2004 and 05 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-29 and 32-45* is/are pending in the application.

4a) Of the above claim(s) *7-9 and 33-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,10-29 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because the typed name of the inventor on page 3 is "Martin T. Martin", whereas the signature under it and all of the communication concerning this application lists the inventor as "Mark T. Martin", which is apparently correct. The application is listed in our computer files as being filed by "Martin T. Martin".

Applicant's election with traverse of Group I, claims 1-16 and 27-33 and the specie "introducing a chemical moiety to said target molecule" in the reply filed on 3/2/05 is acknowledged. The traversal is on the ground(s) that:

(1) Group I is generic to Groups III-VII, with III-VII being species of Group I. "Groups III-XII" (sic, III-VII) define "the type of chemical modification (e.g. by linking, by modulating the activity, by deactivating, etc)".

(2) "[T]he methods of Groups III-VI all relate to the use of a catalytic antibody (claimed in Group I, see e.g. Claim 17)…and also falls within the scope of generic claim 1".

(3) "The method of Group VII merely specifies the type of chemical modification including [sic, included?] within the scope of generic claim 1 (Group I)…[the group] specifies that the type of chemical modification of a target molecule is an attachment of a label".

(4) Applicant previously attempted to elect the species of Group III but were informed in the action mailed 11/26/04 that this had not been listed as a species in the restriction requirement but rather the species of claims

6 and 7. In applicant's reply filed 3/2/05 it is stated that the restriction requirement is traversed "for the same reasons indicated in their Response of October 7, 2004". The examiner construes the argument from this argument concerning election of species to be in the last paragraph of page 3 through the second paragraph of page 4, namely that "[u]nder 37 CFR 1.141, a generic claim, if allowed, may link a reasonable number of species embraced thereby" and that "[e]ven if the examiner rejects the generic claims, and even if the applicant cancels the same and admits that the genus in unpatentable, where there is a relationship disclosed between species, such disclosed relation must be discussed and reasons advanced leading to the conclusion that the disclosed relation does not prevent restriction, in order to establish the propriety of restriction. (See MPEP 808.01(a))."

(5) The examiner has not established a *prima facie* showing that there would be a serious burden upon the examiner to examine all the groups because the methods are closely related and "each of claims 1-16, 27-33 and 34-45 [Group I and III-VII] relate to methods falling within the scope of generic claim 1". Further "it is likely that the same Examiner would be in charge of the divisional applications, but…[he] would have to conduct a duplicate, redundant art search for the divisional applications".

(6) Because "of the GATT legislation limiting the term of a patent to twenty years form its effective filing date, the delay in the examination of the non-elected claims likely would result in the patent term for these claims being unnecessarily shortened".

This is not found persuasive because:

(1) The claims of Groups III-VIII <u>are not</u> species of Group I. The chemical modifications listed *supra* are in claim 6, which is part of group I.

(2) Claim 17 is in group II, not group I as applicant indicates. The

claims of groups III-VI do not depend from claims in either group I or II, but even if these groups relate to the use of the catalytic antibody of group II, as stated in the restriction requirement "the product as claimed can be used in a materially different process such as to modify a target not associated with treating a disease". That is all that is required for a proper restriction.

(3) As stated in the restriction requirement, Group VII is separate and distinct because if modifies the target molecule be attaching a label and none of the other groups do this.

(4) The apparent argument against an election of species recites 37 CFR 1.141, which states that a reasonable number of species be "may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form (§ 1.75) or otherwise include all the limitations of the generic claim". In this case a generic claim has not been indicated as allowable.

(5) It is maintained that there would be a serious burden upon the examiner to examine all of the groups. Not only are the groups classified in different classes and subclasses, but different issues are involved in examining each groups such as 35 USC § 101 and 112 issues. For example the treatment claims involve determining if the treatment has been successfully shown to treat the indicated disease. Therefore the examiner would have different issues to be decided in each application.

(6) The length of a patent issued from an application is not a consideration of the examiner if the restriction was done according to the rules. Applicants can always file divisional application without waiting to see the disposition of the parent application.

Claims 7-9 and 33 are not deemed to read on the elected species of "introducing a chemical moiety to said target molecule" and therefore will not be examined. After reading the instant specification and the instant amendment to the claims, the examiner will examine claims 1-3, 6, 10-29 and 32, which include most of Groups I and II.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7-9 and 33-45 and claims drawn to the invention of Group I not limited to the indicated specie are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/13/04 and 3/2/05.

The disclosure is objected to because of the following informalities:

On page 38, Table 2, "10 g/mL" is in both the second and third columns with slightly different results shown. This is not understood. Are these perhaps two experiments using 10 g/ml? This is not stated in the specification. An explanation is required.

Appropriate correction is required.

Claims 6, 11, 13, 14, 18, 22 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 32 are confusing in that they contain species other than the one elected for prosecution.

Claim 11 is indefinite in the recitation of "claim 4", which claim has been cancelled.

Claims 13 and 22 are confusing and indefinite in the recitation of "(a)" on line 7 and "step (c)" on line 8. Apparently the recitation on line 7 should be "(c)".

Claim 14 is confusing and indefinite in the recitation of "pre-selected". It is not clear what this pre-selection entails nor what it is "pre" to.

Claim 18 lacks antecedent basis for "method of claim 18". Claim 18 is drawn to a catalytic antibody, not a method.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6, 10-29 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification discusses placing a β-lactam antibiotic onto a biologically active molecule using a catalytic antibody. The instant claims are much broader, drawn to "modifying a biologically active target molecule comprising contacting the target molecule with a catalytic antibody capable of chemically modifying said target molecule...under conditions sufficient for said catalytic antibody to modify said target molecule". Although the specification contains many general discussions about antibiotic resistance, the characteristics of various biologically active proteins and various models

for analyzing various disease conditions and molecules, there is not a single example of a catalytic antibody being made and/or isolated in the specification. Therefore it is maintained that one of ordinary skill in the art would not be taught how to make such a catalytic antibody, or if in fact such an antibody could be made, without undue experimentation. While it is acknowledged that working examples are not required for enablement, such examples are greatly preferred. Without such examples the ordinary artisan would not know exactly how to make the antibodies, especially since such antibodies have apparently not been previously been made. One or ordinary skill in the art would not know what to use as a hapten to make such catalytic antibodies.

The specification teaches that one way a catalytic antibody can be made is to use a human phage antibody display library can be panned against the antibiotic-target protein conjugate and the resulting subset then subjected to high throughput screening and directed evolution. It is not understood exactly how this will produce catalytic antibodies. Apparently applicant envision using a conjugate of a protein and antibiotic and screening this against a phage display, and this will produce a catalytic antibody. The specification does not teach even one instance of this ever having been done nor what the results would be. Therefore it is maintained that one of ordinary skill in the art would not know how to make the catalytic antibodies using this procedure. The claims also are drawn to using "*in vivo* selection, and high throughput screening" (claim 11) and "immunizing an animal with a hapten resembling a combining site of said target molecule, alone or in combination with an agent used to chemically modify said target molecule" (claim 12). The *in vivo* selection is further spelled out in claim 13. It is maintained that the specification does not teach the ordinary artisan to perform all of these methods without undue experimentation.

Claims 1-3, 6, 10-29 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As discussed *supra*, the specification does not teach that a single catalytic antibody has ever been produced using the method of the instant claims. Therefore, one of ordinary skill in the art would conclude, after reading the instant specification, that the catalytic antibodies according to the instant claims had not been made nor the methods of the instant claims had not been performed. Without some teaching that applicant possessed the instant invention at the time of filing, it is maintained that the written description requirement has not been met.

Fiers v. Sugano 25 USPQ 1601 (Fed. Cir. 1993) states that "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". *University of California v. Eli Lilly* 43 USPQ2d 1398 (Fed. Cir. 1997) states that the patent specification did not provide a written description of the invention, even though it may have provided an enabling disclosure. The description provided "only a general method for obtaining the human cDNA...along with the amino acid sequences of human insulin A and B chains". It did not provide an written description in that it does not describe human insulin cDNA.

Therefore it is maintained that the instant specification did not provide a written description of the claimed invention such that one of ordinary

skill in the art would conclude that the inventor had possession of the invention at the time of filing.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 6, 17-18, 27-29 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Schochetman, et al. (A). The instant reference teaches the catalysis of a chemical reaction with a catalytic antibody. One of the reactions taught is the cleavage of o-nitropenyl-β-D=galactoside, another teaching is the production of porphobilinogen, the production of L-tryptophan and the cleavage of RNA.

Claims 1-3, 6, 11-12, 17-21, 27-29 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis, et al. (B). Davis et al. teach the

production of catalytic antibodies by phage display that will cleave proteins. Therefore the antibody introduces a water molecule into the protein.

Claims 1-2, 6, 11-12. 17-18, 20-21, 27-28 and 32 are rejected under 35 U.S.C. 102(a or b) as being anticipated by Tanaka, et al. (U). Tanaka, et al. teach selecting by phage display a catalytic antibody that modifies ampicillin by introducing a chemical moiety into the ampicillin, namely two hydrogen molecules. The pharmaceutically acceptable carrier is water or buffer.

Claims 1-3, 6, 17-19, 27-29 and 32 are rejected under 35 U.S.C. 102(b or e) as being anticipated either of Landry (C), Blackburn (V) or Shuster, et. al. (W).

Landry teaches the production of a catalytic antibody that cleaves cocaine. Blackburn also teaches a catalytic antibody that cleavages cocaine and on that cleaves a prodrug. Shuster, et al. teach a catalytic antibody that cleaves DNA. In each instance a water molecule is introduced into the molecule. The pharmaceutically acceptable carrier is water or buffer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
May 2, 2005